COMMISSIONING, VALIDATION & ROUTINE TESTING

FOR

MEDISAFE ULTRASONIC CLEANERS

Introduction

This document is intended to support the Manufacturer's operating instructions already accompanying the machine you have purchased. The validation and verification tests contained within this document are the minimum requirements of Health Technical Memorandum 2030 – (HTM 2030) Guidance on Washer-Disinfectors. These requirements must be complied with in the United Kingdom and are optional elsewhere however; compliance with the guidance will lead to successful use of your equipment.

Objective

To ensure the continued safety & effectiveness of Medisafe Ultrasonic Cleaning Equipment. It is essential that only properly qualified and trained persons carry out tests as specified herein. Medisafe are able to provide competent test persons to undertake routine testing if required.

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5. **Quarterly Tests** detailed in points 4.1 through 5.8 MUST be performed routinely by the test person (These are represented in a logical **sequence Tests 1 through Test 18 Inclusive)**
6. **Annual Tests** detailed in points 4.1 through 6.3 MUST be performed routinely by the test person (These are represented in a logical **sequence Tests 1 through Test 22 Inclusive)**
7. Documentation to be maintained
8. Authorised Signatures
9. Service / Maintenance Agreements available.

1. Key Definitions (As referenced in HTM 2030)

1.1 Authorised Person (Sterilizers)

Defined as a person designated by management to provide independent auditing and advice on sterilizers and sterilisation and to review and witness validation. (See HTM 2010 Part 1 for a full definition of the responsibilities of the Authorised Person (Sterilizers) with respect to sterilizers and the qualifications and experience required). Authorised Persons (Sterilizers) are also able to provide independent auditing and advice on washing and disinfection and WD's and to review and witness validation of these processes and machines. The abbreviation AP(S) is used in this HTM.

1.2 Competent Person

Defined as a person or organisation designated by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a WD described in the 'Pressure Systems and Transportable Gas Containers Regulations 1989'. The shorter term 'Competent Person' is used in this HTM.

1.3 Test Person (Sterilizers)

Defined as a person designated by management to carry out validation and periodic testing of sterilizers. (See HTM 2010 Part 1 for a full definition of the responsibilities of the Test Person (Sterilizers) with respect to sterilizers and the qualification and experience required). Test Persons (Sterilizers) who have received appropriate training should be designated to carry out validation and periodic testing of WDs. The abbreviation TP(S) is used in this HTM.

1.4 Maintenance Person (Sterilizers)

Defined as a person designated by management to carry out maintenance and periodic testing on sterilizers. (See HTM 2010 Part 1 for a full definition of the responsibilities of the Maintenance Person (Sterilizers) with respect to sterilizers and the qualifications and experience required). Maintenance Persons (Sterilizers) who have received appropriate training should be designated to carry out validation and periodic testing of WDs. The abbreviation MP(S) is used in this HTM.

1.5 Microbiologist (Sterilizers)

Defined as a person designated by management to be responsible for advising the user on microbiological aspects of the sterilization of non-medicinal products. They should also be defined as the persons responsible for advising the user on the microbiological aspects of handling, washing and disinfecting used medical devices. The shorter term 'microbiologist' is used in this HTM.

1.6 User

Defined as the person designated by management to be responsible for the management of the WD. In a hospital the user could be a sterile services manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager; in primary care he or she could be a general practitioner, dentist or other health professional. When a WD is used to process equipment or containers for use in the preparation of medicinal products the user is normally the production manager in charge of the manufacturing process.

1.7 Manufacturer

Defined as the person or organisation responsible for the manufacture of a WD.

1.8 Management

Defined as the owner, occupier, general manager, chief executive or other person of similar authority who is ultimately accountable for the operation of the premises. Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small autonomous units the user may take on this function.

2.0 Key to symbols used in this document (Please refer to HTM 2030)

(P) = Process functionality Test
(S) = Safety Test
(TP) = Test Person(s)
(U) = User or Operator
(V) = Process Validation Test

3.0 Installation procedure and performance Qualification tests.

Installation procedure and performance Qualification tests are to be undertaken jointly by manufacturer, test person and user and to be used for commissioning and validation of equipment.

3.1 Installation - (Position the equipment on a firm flat level surface near a suitable electrical power outlet and relevant hot, cold and waste water services.

3.2 (Position & Location) Installation - Ensure that the equipment is in a safe position and refer to the operator's manual for cautionary notes and safe operating instructions.

3.3 (Cold water) Installation - Connect the Cold Water from a suitable quality supply - Ensure the pressure is within the specified range (14 psi to 28 psi).

NOTE: With cold water pressures may be increased to 56 psi but will be subject to the completion of a satisfactory cycle or process to ascertain there is no detrimental effect to the process due to excessive foaming of detergent.

3.4 (Hot Water) Installation - Connect the Hot Water from a suitable quality supply ensure the pressure is within the specified range (14 psi to 28 psi).

3.5 (Drain Waste) Installation - Connect the drain to a minimum 1.5" to 2" (38mm to 50mm) stand pipe - the top of the stand pipe should be better than 6" or (150mm) below the drain valve on the equipment. The drain should be free to air therefore avoiding potential air locks.

3.6 (Power) Installation - Connect the power to the equipment in accordance with the instruction manual whilst paying particular attention to the good reliability of the ground. (Earth)

3.7 (Thermal Disinfection) Installation - If the machine is to be used with the thermal disinfection system - a separate water supply may be used in accordance with HTM2030 notes on water quality.

The equipment has been factory performance tested and set for the validated process as outlined in Medisafe SI Auto/FLC Validation Report. The following tests will also be necessary.

3.81 Sensor operation (Refer to Medisafe Test 11)
3.82 Heater Performance Test (Refer to Medisafe Test 13)
3.83 Ultrasonic Performance Test for Activity (Test 15)
3.84 Cleaning efficacy test using reference test load and test soil (Refer to Medisafe Test 16)
3.85 Drainage (Refer to Medisafe Test 17)
3.86 Thermometric test for thermal disinfection (Refer to Medisafe Test 18)

The operator should be trained how use the equipment competently and also perform the daily checks.

NOTE: COPIES OF THE INSTALLATION AND QUARTERLY / ANNUAL CHECK LISTS SHOULD BE RETAINED BY THE USER - A FURTHER COPY SHOULD BE HELD ON FILE WITH MEDISAFE.

4.0 Daily - TESTS (Notes for use)

DAILY Tests - The daily check list shows routine tests that should be carried out EVERY day of operation - Place a tick in the box to indicate that the particular test has been accomplished and that there is correct function. Should a particular test fail or not function, the relevant person or body should be contacted to make the corrective procedure - check enclosed document for details. The equipment should not be used until the machine is fully operational, notes and documents must be retained in accordance with HTM 2030.

Please observe the enclosed details and expected out come relating to each specific test.

4.1 Test # 1 Use a stiff Nylon Brush (Medisafe part # MED100.33) to remove visible and invisible film on the sensors - use alcohol and scrub vigorously on all three sensors to ensure good contact with water. Use protective eye shields (part # MED100.84) to prevent contaminates and or splashes flicking into the eyes.

4.2 Test # 2 The filter prevents large debris and loose parts being drawn into the machine workings. The filter should be changed every cycle to maintain performance. Filters are available in packs of 100 (part # MED 3080) See users manual for installation and removal instructions.

4.3 Test # 3 - Look for signs of both damage and wear and tear... Make an inspection of both external and internal parts. Leaks will be seen as small puddles on or around the base of the machine.

DO NOT MISTAKE puddles that form as a consequence of opening and shutting the lid and loading and unloading the basket. - Damage and wear and tear should be reported to the supervisor or departmental manager.

4.4 Test # 4 - Make an inspection to ensure that the HOT and COLD water supply is turned ON and functioning properly without leaks. Damage and wear and tear or incorrect function should be reported to the supervisor or departmental manager.

4.5 Test # 5 - Check to make sure the drain hose is in position and functional and that there are no restrictions or kinks that would prevent the machines operation. - Damage and wear and tear or incorrect function should be reported to the supervisor or departmental manager

4.6 Test # 6 - FOR VALIDATED CYCLE - ONLY USE 3E-ZYME - The machines performance has been measured using 3E-Zyme detergent (part # MED 8035) - check there is sufficient volume (under normal operating performance 1 gallon of 3E-Zyme will last 25 cycles) for the day. Change bottles where appropriate - ensure detergent "pick up" hose is in the correct position and in the appropriately labelled port.

4.7 Test # 7 - (IF USED) Check there is sufficient lubricant volume. Change bottle where appropriate. - Ensure lubricant "pick up" hose is in the correct position and in the appropriately labelled port.

4.8 Test # 8 - As detailed in HTM2030 9.253 to 9.256 & 9.257 to 9.259 respectively Check that the machines lid locking / interlocking mechanism is working correctly - the lid indicator light should be ON when the lid is closed. The machine should automatically pause when the front of the lid is raised by >20mm - If the equipment is fitted with an electronic lock it should not be possible to open the lid during the machines cycle or when the power is switched off.

4.9 Test # 9 - Make a visual check for any discoloration (whitening of the luer tubes), loose fitting tubes over the nozzles) or broken parts that are used to connect the machine to the basket also the basket to the instruments. Replace parts as necessary. Replacement plumbing kit (part # MED 1013.6)

SIGN OFF - DAILY - The Competent Person must sign off the daily checks to verify the functionality of the machine against the tests 1 through 9.

SIGN OFF - MONTHLY - The designated test person should check that the competent user has duly completed the daily checks throughout the month. The page detailing the months tests should be then signed and kept in accordance with the **requirements for HTM 2030.**

5.0 Quarterly & Annual Tests (Notes for use)

QUARTERLY & ANNUAL (Installation) Tests - The quarterly/annual checklist shows a number of routine tests and performance tests that MUST ONLY be carried out by a qualified person. The tests must be carried out every quarter with other specific test being carried out annually. A tick should be placed in the box to indicate that the particular test has been accomplished and that the relevant performance characteristics have been observed. Should a particular test fail or not function the relevant person or body should be contacted to make the corrective procedure - the equipment should not be used until the machine is fully operational - check enclosed document for details. The department and the authorised testing organisation should retain notes and documentation.

Please observe the enclosed details and expected outcome relating to each specific test.

5.1 Test # 11 - Check the correct operation of the machines low, full and overflow sensors by using the machines test mode function. Fill the machine to ascertain the correct electrical switching operation of machines sensors - Check the overflow sensor by dipping a wire or metal object into the tank water and touching the overflow sensor with the other end. Report any non-conformance and subsequent corrective action.

5.2 Test # 12 - Using the machine's test mode, check flow and pressure of each CPE pulsation unit. Use either a flow meter or measuring beaker and stopwatch. It should take NO LONGER than 22 seconds to pass 1 quart of water. Therefore flow rates in excess of 1 quart per 30 seconds is acceptable. The pressure measured at each port should be 28psi. Report any non-conformance and subsequent corrective action.

N/A → 5.3 Test # 13 - Using the machines test mode, check the operation of the booster heaters and that the correct current is drawn (approximately 1.55 Amps +/- 10% @ 230V). Report any non-conformance and subsequent corrective action.

Run 3-5min Before this test OR Tosi strip

5.4 Test # 14 - Using the machine's test mode, check for ultrasonic activity by using the "Foil Test" outlined in HTM2030 - 19.0 "specific tests for ultrasonic cleaners" attach and retain the strips for future reference. Alternatively run a "Cavi-matt" computerised ultrasonic activity test and measure the current drawn by the ultrasonics - printout and retain the graph. Record the performance and current data ensuring it is in accordance with the original specification. Report any non-conformance and subsequent corrective action.

N/A → 5.5 Test # 15 - Use current measuring software to plot a graph of the current drawn during cycle 1. Make a comparison against the original (ex factory) current performance graph and ensure there are no significant deviations. Report any non-conformance and subsequent corrective action.

N/A → 5.6 Test # 16 - As described in HTM2030 19.0 "specific tests for ultrasonic cleaners" load the machine with the specified & soiled instruments using the soil outlined in 19.22 or equivalent - run the standard validated cycle. Observe the results in accordance with HTM2030 19.28. Report any non-conformance and subsequent corrective action.

5.7 Test # 17 - In accordance with HTM2030 9.38 / 9.39 (Residual water) Remove Filter - Fill the machine using clean water in the machines test mode - when full switch the machine off - and then on. Check the drain evacuation efficiency by measuring the time taken to drain the tank fully, this should not exceed 3.5 minutes - ensure that the extended drain time function is operational. Report any non-conformance and subsequent corrective action.

N/A → 5.8 Test # 18 - Thermometric Testing as specified in HTM 2030 9.316 making provision for the specific requirements of ultrasonic cleaners - should be carried out during the wash phase and disinfection/rinse phases.

SIGN OFF - QUARTERLY - The departmental manager or supervisor should check that the qualified engineer has duly completed the quarterly checks. The page detailing the quarterly tests should be then signed by both the engineer and departmental manager and kept in accordance with the requirements for HTM 2030.

6.0 MEDISAFE - Annual Checks (To include Quarterly & Daily tests):

6.1 Test # 20 - In accordance with HTM2030 9.282 to 9.284 "reproducibility of volume admitted" Using the machines test mode, check dosing of the 3E-Zyme detergent system. Use either a flow meter or measuring beaker and stopwatch. Fill a beaker with 500 ml of 3E-Zyme and observe that a quantity of 160 ml of fluid are removed in 10 seconds. Report any non-conformance and subsequent corrective action.

6.2 Test # 21 - In accordance with HTM2030 9.282 to 9.284 "reproducibility of volume admitted" Using the machines test mode, check dosing of the Lubricant system. Use either a flow meter or measuring beaker and stopwatch. Fill a beaker with 500 Ml of E-Zee Lube and observe that a quantity of 160 ml of fluid are removed in 10 seconds. Report any non-conformance and subsequent corrective action.

N/A 6.3 Test # 22 - Using the machines test mode, check for ultrasonic activity by using the "Cavi -matt" computerised ultrasonic activity test and make a comparison against the ex-factory original specification. Also measure the current drawn by - and temperature of - the APG Ultrasonic Generator. Report any non-conformance and subsequent corrective action.

SIGN OFF - Annual - The Authorised Person should check that the test person has duly completed the Annual checks. Both the Authorised Person and test person and or the manufacturer in accordance with the requirements should then sign the page detailing the quarterly and annual tests for HTM 2030.

NOTE: COPYS OF THE INSTALLATION AND QUARTERLY/ANNUAL CHECK LISTS SHOULD BE RETAINED BY THE USER - A FURTHER COPY SHOULD BE HELD ON FILE WITH MEDISAFE

SIGN OFF - DAILY - The Competent Person must sign off the daily checks to verify the functionality of the machine against the tests 1 through 9.

SIGN OFF - MONTHLY - The designated test person should check that the competent user has duly completed the daily checks throughout the month. The page detailing the month's tests should be then signed and kept in accordance with the requirements for HTM 2030.

SIGN OFF - ANNUAL - The Authorised Person should check that the test person has duly completed the annual checks. The Authorized Person and Test Person and or the Manufacturer in accordance with the requirements should then sign the page detailing the quarterly and annual tests for HTM 2030.